CONSUMER NEWS
SAN DIEGO CITY ATTORNEY'S OFFICE

Cosmetics Safety

November 2009

The Federal Food, Drug and Cosmetic Act defines "cosmetics" as "articles intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting the body's structure or functions."

Included within this definition are skin creams, lotions, perfume, lipstick, fingernail polish, eye and facial make-up, shampoo, permanent waves, hair dye, toothpaste, and deodorant.

Cosmetic products that are also intended to treat or prevent disease, or to affect the structure or function of the body are considered drugs. Examples of cosmetic/drugs include fluoride toothpaste, moisturizers with sunscreen, antiperspirants that are also deodorants, antidandruff shampoos, and lip balm.

HOW ARE COSMETICS REGULATED?

FEDERAL LAW:

Cosmetics marketed in the U.S. must comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA). These laws provide that the Food and Drug Administration (FDA) regulates the manufacture and sale of cosmetics.

What is the FDA's authority over cosmetics?

The FD&C Act requires cosmetics marketed in interstate commerce to be safe (when used as directed) and prohibits marketing adulterated (harmful) products. The FPLA prohibits the misbranding (incorrectly or deceptively labeling or filling) of cosmetics.

The FDA may conduct product investigations, inspect establishments in which products are manufactured, and seize adulterated or misbranded cosmetics. The FDA may also pursue legal action through the Department of Justice to request a restraining order against the manufacturer of an adulterated or misbranded product.

Violations of these federal laws which occur in the City of San Diego can also be prosecuted by the San Diego City Attorney's Consumer & Environmental Protection Unit.

What are the limits of the FDA's authority?

Unlike drugs, cosmetics are not subject to pre-market approval by the FDA. The FDA does not require manufacturers to test their products for safety, and may not order a recall of a cosmetic it finds unsafe or defective. Further, the FDA does not require manufacturers to register their cosmetics, file data on ingredients, or report cosmetic-related injuries.

*When is a cosmetic **adulterated**?*

Under the FD&C Act, a cosmetic is adulterated when it:

- Contains a substance which may make the product harmful to consumers under customary conditions of use.
- Contains any filthy, putrid, or decomposed substance.

- Was prepared, packed, or held under insanitary conditions; or
- Contains an unsafe color additive (with the exception of hair dyes).

*When is a cosmetic **misbranded**?*

Under the FPLA, a cosmetic is considered misbranded if:

- It is labeled in a false or misleading way.
- It is missing the name or place of business of the manufacturer, packer, or distributor.
- It is missing an accurate statement of the quantity of contents (weight, measure, or numerical count).
- Its required label information is not stated prominently in terms understood by consumers.
- Its container is misleading.

Additional Labeling Requirements:

- All required labeling information must be in English.
- The label must identify the name, nature, and use of the cosmetic.
- The label should be large enough to accommodate all mandatory information without being obscured by designs or crowding.
- All type in the information panel should be larger than 1/16th of an inch in height.
- Cosmetic ingredients must be listed in descending order of predominance.
- Ingredients present in insignificant levels having no functional effect do not need to be listed.
- Cosmetics used solely for professional use (in salons, etc.) that are not sold to consumers do not need to list ingredients on their labels.
- When a cosmetic is also an over-the-counter drug, the label must list the active drug ingredients first, then the cosmetic ingredients.

Warning Requirements:

- Cosmetic labels must contain a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product.
- This warning must be conspicuous by appearing in bold type on a contrasting background.
- If the cosmetic manufacturer has not substantiated the safety of its product pre-market, the label must state "Warning—The safety of this product has not been determined."
- Additional, specific warnings are required for cosmetics in self-pressurized containers, products containing halo- or hydrocarbons (to prevent "huffing"), deodorant sprays, children's bubble bath products, coal tar hair dyes posing a risk of cancer, and sun tanning aids.

CALIFORNIA LAW:

In California, the Sherman Food, Drug, and Cosmetic Act makes it a state crime to violate the federal FD & C and FPLA.

In 2005, the California Legislature passed the California Safe Cosmetics Act, requiring manufacturers with national sales of over $1million who sell cosmetics in California, to provide the State Department of Health Services (DHS) with a list of their products containing an ingredient identified as causing cancer or reproductive toxicity. (Ingredients fitting this description are published yearly by the governor under CA Prop 65). The reporting deadline for companies to be in compliance is Dec. 15, 2009.

MORE INFORMATION ABOUT COSMETIC SAFETY?

The Environmental Working Group provides an online Cosmetic Safety Database. The site contains safety information about thousands of cosmetic products and rates products based on known information. To check out your own cosmetics, go to www.cosmeticsdatabase.com.

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Newsletter written by Jen Gustafson.

To report violations of consumer protection laws, call the City Attorney's Hotline at **(619) 533-5600.**